REMARKS

Claim 1-6 are pending in the instant application. Claims 3 and 5 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Claims 1, 2, 4 and 6 have been rejected. Claim 1 has been amended and claims 2, 4 and 6 have been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed March 26, 2002. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have canceled non-elected claims 3 and 5 without prejudice. In light of the finality of the Restriction Requirement, Applicants reserve the right to file a divisional application to the canceled subject matter.

II. Objection to Claims 1, 2, 4 and 6

Claims 1, 2, 4 and 6 have been objected to as being drawn in part to a non-elected invention. Accordingly, in an earnest effort to advance the prosecution of this case, claim 1 has been

amended to be drawn only to the elected subject matter. Claims 2, 4 and 6 have been canceled.

Claims 1, 2 and 4 have also been objected to for use of the language "associated". Thus, in accordance with the Examiner's suggestion, Applicants have amended claim 1 to state "indicative of". Claims 2 and 4 have been canceled.

In addition, claim 6 is objected to as depending on non-elected claims. Claim 6 has been canceled thus mooting this objection

Withdrawal of these objections is respectfully requested in light of the amendments to the claims.

III. Rejection of Claims 1, 2, 4 and 6 under 35 U.S.C. § 112, first paragraph - Lack of Enablement

Claims 1, 2, 4 and 6 have been rejected under 35 U.S.C. § 112, first paragraph. The Examiner has acknowledged the specification to be enabling for a method of diagnosing the presence of prostate cancer comprising measuring levels of the polynucleotide of SEQ ID NO:1 in prostate cancer tissue, wherein an increase in these levels indicates the presence of prostate cancer. However, the Examiner suggests that the specification does not reasonably provide enablement for a method for diagnosing prostate cancer, or metastatic prostate cancer or the

onset of metastatic prostate cancer, comprising measuring the "levels of PSG, which is the levels of the PSG polypeptide encoded by the polynucleotide of SEQ ID NO:1", in a "sample of any cell, any tissue or any bodily fluid" obtained from a patient, wherein an increase in the levels of PSG is associated with the presence of prostate cancer or a cancer which has metastasized.

Accordingly, in an earnest effort to advance the prosecution of this case, and in light of the Examiner's acknowledgment of enabled subject matter, Applicants have amended claim 1 to clarify that the PSG measured comprises the nucleic acid SEQ ID NO:1. Claim 6 has been canceled in light of this amendment. Further, Applicants have canceled claims 2 and 4 drawn to methods for diagnosing and monitoring metastatic prostate cancer.

Applicants have also amended claim 1 to state that the PSG levels are measured in a prostate cells or prostate tissue or a bodily fluid.

With respect to detection in bodily fluids, it is respectfully pointed out that comments by the Examiner in the Office Action that "it is unpredictable that prostate cancer cells . . could be detected" are not relevant to the instant claimed invention. Claim 1 of the instant application is drawn

to measuring levels of PSG comprising SEQ ID NO:1, not detecting prostate cells.

Also irrelevant are comments by the Examiner regarding the possibility that the prostate cancer cells may not be in bodily fluids such as tracheobronchial tree, the gastrointestinal tract, the bladder, cerebro-spinal fluid and aqueous humor of the eye and that the specification does not disclose that prostate cancer cells are found in bodily fluids such as tracheobronchial tree, the gastrointestinal tract, the bladder, cerebro-spinal fluid and the aqueous humor. MPEP § 2164 is quite clear; to meet the enablement requirements the information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to make and use the claimed invention. Those skilled in the art recognize the types of bodily fluids routinely tested for diagnostic cancer markers, and more particularly prostate cancer markers. Bodily fluids such as the tracheobronchial tree, the gastrointestinal tract, the bladder, cerebro-spinal fluid and the aqueous humor are not routinely tested by those skilled in the art for diagnostic cancer markers, particularly prostate cancer markers. Further, the specification at page 11, lines 6-14 teaches exemplary bodily fluids tested routinely by those skilled in this art field to

detect prostate cancer markers.

MPEP § 2164.01 states that as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claimed, then the enablement requirement of 35 U.S.C. § 112, is satisfied. As discussed in the preceding paragraph, exemplary bodily fluids used routinely by those of skill in the art are taught at page 11, lines 6-14. Further, methods for detecting the claimed PSG are taught in detail at page 8, line 31 through page 11, line 5. These teachings clearly disclose multiple methods for making and using the claimed invention and bear a reasonable correlation to the entire scope of the claimed, thus satisfying the enablement requirement of 35 U.S.C. § 112..

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly,

favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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Date: February 6, 2004

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